



Senator Feinstein Expresses Concern Over FDA's Approval of Silicone Gel Breast Implants

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Washington, DC – U.S. Senator Dianne Feinstein (D-Calif.) today voiced concern over the U.S. Food and Drug Administration announcement that final approval has been granted for the silicone gel breast implants produced by Allergan and Mentor Corporation.

“The FDA announced this afternoon that it has ended its 14-year ban on silicone gel breast implants and approved products by Allergan and Mentor Corporation,” Senator Feinstein said. **“Serious questions remain about the long-term safety of these products. The FDA has a responsibility to carefully monitor the health and safety of women who use these implants.”**

Senators Feinstein and Olympia Snowe (R-Maine) last month sent a letter to FDA Acting Commissioner Andrew von Eschenbach, calling for a full review of product testing data before final approval of Mentor Corporation's implant was granted. The Senators cited recent reports that revealed Mentor may have unreported data and inaccuracies regarding dangerous leakage from the company's silicone gel breast implants.

The Senators wrote in their October 20 letter: “No medical device should be granted final approval if data that could reveal potential dangers has not been fully investigated and analyzed. The health and safety of American women should be the top concern of your agency as the approval process moves forward.”

The Senators have yet to receive a response to their letter.

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